

Kinser, Robin D.

From: Kinser, Robin D.
Sent: Thursday, March 21, 2002 9:00 PM
To: Don Leyden (E-mail)
Cc: Kinser, Robin D.
Subject: a box-and-whisker plot

Dear Don-

This is the technical message I promised sometime ago. I wanted to let you know my perspective on the nicotine data issues, and hopefully help you realize your scientific reputation was never in jeopardy.

The SRNT meeting came up at a Clinical Eval staff meeting the 2nd week of December. I responded with great negativity to the prospect of our submitting an abstract for this meeting, pointing out that we didn't have data yet, and it would have us reporting data very quickly after its receipt, etc., etc. I was about as obnoxious as I can be, but I was overruled. I drafted an abstract that was completed and submitted as I recovered from the embolism. The abstract did not "predict" results, merely outlined what we would discuss.

When the data listings were obtained, a great flurry of activity ensued, as you can imagine. The items I think were most responsible for Tony's anxiety were substituting the LLOQ for the values <LLOQ, which led to what was probably an exaggeration of the non-smoker values. Secondly, we found that the cotinine levels of two of our "non-smokers" exclude them from being non-smokers, but we did not have the confirmatory data from the diaries and butt collection to confirm that hypothesis. Hence the decision to report only smoker data at that time. Lastly, our colleagues doing calculations and conversions from moles to grams and back did not have the intuitive grasp most chemists do regarding order of magnitude of those conversions, or the intuition experienced tobacco scientists have regarding order of magnitude of cigarette smoke constituents. Tables were generated too rapidly, and shared without proper proofreading, so that on at least one occasion data indicating grams of nicotine excretion per day were created and emailed to authors. For that particular example, the only error was in the y-axis label, which was milligrams instead of micrograms. Of course, these calculations were all originally planned to be the CRO's responsibility and we had not prepared to conduct these data analyses ourselves.

So I've not sent you data because I've been concerned about how much space our graphics from SRNT make take up—we didn't do tables, just box-and-whisker plots and regressions of total nic equiv vs. cigarettes/day. I am going to attach one of the box-and-whisker plot to this message and you can let me know how crippling it was. Data reports are due from the CRO in a few weeks.

Of course I still miss conversations with you and Alice. I've spoken recently with Keith Phillips and Bob Libby, both of whom send their regards. Let me know if I have to reimburse you for this download when you return.

Robin